PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

SHIMIZU, Hatsushi
Kantetsu Tsukuba Bldg. 6F
1-1-1, Oroshi-machi
Tsuchiura-shi, Ibaraki
3000847
JAPON

Date of mailing *(day/month/year)* 03 August 2006 (03.08.2006)	
Applicant's or agent's file reference D3-A0307Y1P	**IMPORTANT NOTIFICATION**
International application No. PCT/JP2004/016089	International filing date *(day/month/year)* 29 October 2004 (29.10.2004)
Applicant DNAVEC RESEARCH INC. et al	

1. **Transmittal of the translation to the applicant.**

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

EP, KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
D3-A0307Y1P		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/016089	29.10.2004	04.11.2003

International Patent Classification (IPC) or national classification and IPC

C12N15/09, C12N5/16, A61K39/00, A61K48/00, A61P35/00

Applicant

DNAVEC RESEARCH INC.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/016089

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/016089

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 13,14

because:

☒ the said international application, or the said claims Nos. 13,14
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The invention set forth in claims 13 and 14 corresponds to a method for the treatment of the human body by means of therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13,14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/016089

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: C. H. JIN, Y. YONEMITSU and S. OKANO, et al., "Recombinant Sendai virus provides a highly efficient gene transfer into human cord blood-derived hematopoietic stem cells," Gene Ther., February 2003, Vol. 10, No. 3, pages 272 to 277

Document 2: H. JONULEIT et al., "Efficient transduction of mature CD83+ dendritic cells using recombinant adenovirus suppressed T cell stimulatory capacity," Gene Ther., 2000, Vol. 7, No. 3, pages 249 to 254

Document 3: H. SUMIMOTO, et al., "Rapid and efficient generation of lentivirally gene-modified dendritic cells from DC progenitors with bone marrow stromal cells," J. Immunol. Methods, 2002, Vol. 271, No. 1-2, pages 153 to 165

Document 4: A. LUNDQVIST, et al., "Nonviral and viral gene transfer into different subsets of human dendritic cells yield comparable efficiency of transfection," J. Immunother., 2002, Vol. 25, No. 6, pages 445 to 454

Document 5: S. OKANO, et al., "Recombinant Sendai virus

vectors for activated T lymphocytes," Gene Ther., August 2003, Vol. 10, No. 16, pages 1381 to 1391

Claims 1 to 12

The inventions set forth in claims 1 to 12 do not involve an inventive step in the light of documents 1 and 3.

Document 1 indicates that it is possible to insert a GFP into a CD34+ cell derived from human cord blood, which is to say a hematopoietic stem cell derived from human cord blood, by means of the Sendai virus vector.

Meanwhile, document 3 indicates that dendritic cells were created by inserting GFPs into CD34+ cells from cord blood by means of HIV virus vectors and then culturing said cells in a culture medium that contains SCF, GM-CSF, TNF-α and IL-4.

In the description of the present application, example 6 from the section titled 'A. An Investigation of the Introduction Efficiency' (refer to paragraph [0119]) indicates that "there is a report pertaining to other virus vectors which indicates that transgenic dendritic cells were created by inserting a gene into a CD34 cell and then inducing dendritic cell differentiation (J. Immunol. Methods, 2002, pages 153 to 165; document 3), and thus a similar method was attempted using the SeV-GFP." Therefore, it is considered to have been easy for a person skilled in the art to conceive of using the Sendai virus vector in order to insert a target gene into a CD34+ cell derived from cord blood, as disclosed in document 1, and then inducing the differentiation of said transgenic CD34+ cell into a dendritic cell by means of

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

the method disclosed in document 3. When inserting a target gene by means of gene therapy, a person skilled in the art could select genes that encode cytokines, which are well-known proteins that are employed in the treatment of cancer and the like, as the target genes to be inserted into the Sendai virus vector, as appropriate.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 to 8 and 10 to 14 set forth inventions related to a "method for the production of transgenic dendritic cells, which includes a step for bringing a negative strand RNA virus vector into contact with dendritic cells or dendritic cell precursor cells." However, the specific examples of the production of the abovementioned dendritic cells or dendritic cell precursor cells employ only the Sendai virus vector, and not any other negative strand RNA virus vector.

Given the abovementioned disclosures in the description, the description does not include sufficient support for the inventions set forth in the abovementioned claims, wherein the method for the production of transgenic dendritic cells includes a step for bringing any negative strand RNA virus vector into contact with dendritic cells or dendritic cell precursor cells.

Consequently, the search focused on the portions of the inventions set forth in the claims which are also set forth and supported in the description; i.e., the examples.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/016089

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☒ contained in the international application as filed

   ☐ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*